SEP 0 9 2009

5.0 510(k) SUMMARY

SUBMITTED BY:

Kelly R. Sauer
Regulatory Affairs Specialist
DiaSorin Inc.
1951 Northwestern Avenue
P.O. Box 285
Stillwater, MN 55082-0285
Phone (651) 439-9710
Fax (651) 351-5669
Email: kelly.sauer@diasorin.com

NAME OF DEVICE:

Trade Name:	LIAISON® 25 OH Vitamin D TOTAL Calibration Verifiers
Common Names/Descriptions:	Vitamin D TOTAL Assayed Quality Control Materials
Classification Names:	Single (Specified) Analyte Controls (Assayed and Unassayed)
Classification Number:	21CFR 862.1660
Product Code:	JJX

PREDICATE DEVICES : LIAISON® 25 OH Vitamin D TOTAL Control Set Reference K071480

DEVICE DESCRIPTION:

INTENDED USE:
The DiaSorin LIAISON® 25 OH Vitamin D TOTAL Calibration Verifiers are assayed quality control materials intended for *in vitro* diagnostic use in the quantitative verification of calibration and reportable range of the LIAISON® 25 OH Vitamin D TOTAL Assay when performed on the LIAISON® Analyzer.

KIT DESCRIPTION:
The LIAISON® 25 OH Vitamin D TOTAL Calibration Verifiers consist of four human serum-based total vitamin D levels with buffer salts and sodium azide. Each vial contains 5.0 mL of ready to use liquid material. The set is provided with targeted total vitamin D concentrations. The individual Calibration Verifier concentrations were chosen to represent values closest to the important decision limits used to determine Vitamin D sufficiency status in individual patients.

PERFORMANCE DATA:

REPRODUCIBILITY

Precision studies were conducted to verify the DiaSorin established performance of the LIAISON® 25 OH Vitamin D TOTAL Calibration Verifiers. Three Calibration Verifier lots were tested on 3 LIAISON® Analyzers. Each Calibration Verifier (A-D) was tested in quadruplicate, one run per day for 5 days. CLSI EP15-A2 was consulted in the study design. The LIAISON® 25 OH Vitamin D TOTAL Controls were tested as daily quality control for the assay.

The mean, standard deviation (SD), and coefficient of variance (%CV) for within run, between run, total by instrument, and overall were computed for each of the tested Calibration Verifiers.

Table 1: 5 day Precision study results

Cal Verifier		Expected Range	mean conc	Within run		Between run		Total (by instrument)		overall	
ID#	N	ng/mL	ng/mL	SD	%CV	SD	%CV	SD	%CV	SD	%CV
A Lot #1	60	7.1 - 13.3	10.5	0.66	6.4	1.19	11.3	1.26	12.0	1.35	12.9
B Lot #1	60	29.9 - 48.9	41.9	1.98	4.8	3.44	8.2	3.70	8.8	3.71	8.9
C Lot #1	60	54.5 - 81.7	71.4	2.33	3.3	5.54	7.7	5.59	7.8	5.66	7.9
D Lot #1	60	92.9 - 139.3	122.6	4.04	3.3	9.55	7.8	9.72	7.9	9.63	7.9
A Lot #2	60	7.1 - 13.3	9.7	0.64	6.5	1.36	14.1	1.39	14.4	1.42	14.6
B Lot #2	60	30.7 - 50.1	40.3	2.15	5.3	3.99	9.9	4.29	10.6	4.23	10.5
C Lot #2	60	56.6 - 85.0	72.4	3.23	4.5	5.14	7.1	5.78	8.0	5.86	8.1
D Lot #2	60	90.5 - 135.7	116.3	4.01	3.5	6.84	5.9	7.56	6.5	8.01	6.9
A Lot #3	60	7.9 - 14.7	10.6	0.61	5.8	0.91	8.6	1.03	9.7	1.03	9.7
B Lot #3	60	32.9 - 53.6	40.7	2.37	5.8	1.88	4.6	2.90	7.1	3.18	7.8
C Lot #3	60	59.0 - 88.5	67.9	2.60	3.8	2.59	3.8	3.43	5.0	3.76	5.5
D Lot #3	60	97.2 - 145.8	111.1	3.64	3.3	3.99	3.5	5.41	4.8	6.51	5.9

COMPARISON TO PREDICATE DEVICE:

The following table compares the LIAISON® 25 OH Vitamin D TOTAL Calibration Verifiers to LIAISON® 25 OH Vitamin D TOTAL Control Set.

Table1: Table of Similarities

Characteristic	Predicate Device LIAISON® 25 OH Vitamin D TOTAL Control Set K071480	New Device LIAISON® 25 OH Vitamin D TOTAL Calibration Verifiers
Intended Use	Assayed quality control samples to monitor the accuracy and precision of the DiaSorin LIAISON® 25 OH Vitamin D TOTAL Assay	Assayed quality control materials for *in vitro* diagnostic use in the quantification verification of calibration and reportable range of the DiaSorin LIAISON® 25 OH Vitamin D TOTAL Assay when performed on the LIAISON® Analyzer
Analyte	Total 25-hydroxyvitamin D	Total 25-hydroxyvitamin D
Format	Provided ready to use Liquid	Provided ready to use Liquid
Product Handling	Transfer 250 µL to test tube and place on LIAISON® Analyzer Discard unused portion	Transfer 250 µL to test tube and place on LIAISON® Analyzer Discard unused portion
Processing	Automated LIAISON® Analyzer	Automated LIAISON® Analyzer
Product Storage	2 to 8°C	2 to 8°C
Required Reagent	LIAISON® 25 OH Vitamin D TOTAL Assay	LIAISON® 25 OH Vitamin D TOTAL Assay
Matrix	Vitamin D free human serum with buffer salts and <0.1% sodium azide	Vitamin D free human serum with buffer salts and <0.1% sodium azide

Table 2: Table of Differences		
Characteristic	**Predicate Device LIAISON® 25 OH Vitamin D TOTAL Control Set K071480**	**New Device LIAISON® 25 OH Vitamin D TOTAL Calibration Verifiers**
Levels	Two	Four
Volume	4.0 mLs	5.0 mLs

CONCLUSION:

The material submitted in this premarket notification is complete and supports the substantial equivalence of the LIAISON® 25 OH Vitamin D TOTAL Calibration Verifiers to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 09 2009

Diasorin, Inc.
c/o Ms. Kelly R. Sauer
Regulatory Affairs Specialist
1951 Northwestern Avenue
P. O. Box 285
Stillwater, MN 55082-0285

Re: k090104
Trade Name: Liaison 25 OH Vitamin D Total Calibration Verifiers
Regulation Number: 21 CFR §862.1660
Regulation Name: Single (Specified) Analyte Controls (Assayed and Unassayed)
Regulatory Class: Class I, reserved
Product Codes: JJX
Dated: July 27, 2009
Received: July 29, 2009

Dear Ms. Sauer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K090104

Device Name: LIAISON® 25 OH Vitamin D TOTAL Calibration Verifiers

Indication For Use: The DiaSorin LIAISON® 25 OH Vitamin D TOTAL Calibration Verifiers are assayed quality control materials intended for *in vitro* diagnostic use in the quantitative verification of calibration and reportable range of the LIAISON® 25 OH Vitamin D TOTAL Assay when performed on the LIAISON® Analyzer.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) ___K090104___